AUG 16 2005

K051633

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck
7002 South 109th Street
La Vista, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402) 537-5313

Date Prepared: July 15, 2005

Names of Device:

Trade Name:	**CD-Chex® Plus BC**
Common Name:	Immunophenotyping Control
Classification Name:	White Cell Control, 21CFR864.8625

Predicate Device: CD-Chex® Plus (K960894)

Description:

CD-Chex Plus BC is a suspension of stabilized human red blood cells and human white blood cells packaged in a plastic vial containing 3.0 mL volumes. The vials are packaged in a vacuum formed "clam-shell" box.

Intended Use:

CD-Chex Plus BC is designed to serve as a quality control specimen for clinical flow-cytometric procedures performed with Beckman Coulte® flow cytometry instruments.

Comparison with Predicate Device:

Like CD-Chex Plus, CD-Chex Plus BC is intended to enable the user to verify satisfactory performance of flow cytometry systems. Both devices contain control cells which possess surface antigens detectable with monoclonal antibodies.

Unlike CD-Chex Plus, CD-Chex Plus BC has a shorter closed vial stability. CD-Chex Plus BC closed vial stability is 60 days, where CD-Chex Plus is 90 days. The other difference is that CD-Chex Plus BC has two components that are used generally for stabilizing cellular components that are at a higher concentration than CD-Chex Plus. This allows the product to work optimally with Coulter and BC FACSCount flow cytometry systems.

Testing Performed:

Three studies of CD-Chex Plus BC were conducted: 1) Closed Vial Stability; 2) Open Vial Stability; and 3) Alternate Site Testing. Study results showed CD-Chex Plus BC to be consistently reproducible and stable for the entire product dating.

Conclusions Drawn from the Tests:

Study results show CD-Chex Plus BC to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating. CD-Chex Plus BC is a safe and effective product, which fulfills its intended use when used as instructed in the product package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2005

Ms. Carol Thompson
Quality Assurance Manager
Streck
7002 South 109th Street
La Vista, Nebraska 68128

Re: k051633
Trade/Device Name: CD-Chex® Plus BC
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology Quality Control
Regulatory Class: II
Product Code: GGL
Dated: July 21, 2005
Received: July 22, 2005

Dear Ms. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051633

Device Name: **CD-Chex® Plus BC**

Indications For Use:

CD-Chex Plus BC is designed to serve as a quality control specimen for clinical flow-cytometric procedures performed with Beckman Coulter® flow cytometry instruments.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

JP Reeves for J. Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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